



engage in the commercial manufacture, use, or sale of Estradiol Vaginal Tablets, 10 µg (“Teva’s ANDA Product”), prior to the expiration of U.S. Patent Nos. 7,018,992 (“the ‘992 patent”) and 5,860,946 (“the ‘946 patent”). The remaining allegations in paragraph 1 of the Complaint state conclusions of law and therefore no response is required from Teva. Further answering, Teva states that the patents speak for themselves.

### **THE PARTIES**

2. Teva is without information sufficient to admit or deny the allegations in paragraph 2 of the Complaint and therefore denies the same.

3. Teva is without information sufficient to admit or deny the allegations in paragraph 3 of the Complaint and therefore denies the same.

4. Teva admits that Teva is a corporation organized and existing under the laws of the State of Delaware. Teva denies that it has a principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044. Teva’s principal place of business is at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva admits that it is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. Teva admits that it has previously filed lawsuits and asserted counterclaims in lawsuits filed in this Court. Teva also admits that in prior litigations, it has submitted to the jurisdiction in this Court for the purposes of those particular litigations. Teva denies the remaining allegations of paragraph 4 of the Complaint.

### **JURISDICTION AND VENUE**

5. Teva admits the allegations of paragraph 5 of the Complaint.

6. For the purposes of this case, Teva admits that this Court has personal jurisdiction over Teva. Teva denies the remaining allegations in paragraph 6 of the Complaint.

7. For the purposes of this case, Teva admits that venue with respect to Teva is

proper in this judicial district.

**THE PATENTS-IN-SUIT**

8. Teva admits that according to the face of the ‘992 patent, the ‘992 patent is entitled “Hormone Composition” and issued on or about March 28, 2006. Teva admits that what appears to be a true and correct copy of the ‘992 patent was attached to the Complaint as Exhibit A. Teva admits that according to the face of the ‘992 patent, the ‘992 patent is assigned to Novo Nordisk A/S. Teva admits that on October 24, 2012, NNFCAG filed a reissue application, which is pending as United States Application No. 13/659,605. Teva is without information sufficient to admit or deny the remaining allegations in paragraph 8 of the Complaint and therefore denies the same.

9. Teva admits that according to the face of the ‘946 patent, the ‘946 patent is entitled “Instrument for Inserting a Suppository” and issued on or about January 19, 1999. Teva admits that what appears to be a true and correct copy of the ‘946 patent was attached to the Complaint as Exhibit B. Teva admits that according to the face of the ‘946 patent, the ‘946 patent is assigned to Novo Nordisk A/S. Teva is without information sufficient to admit or deny the remaining allegations in paragraph 9 of the Complaint and therefore denies the same.

**VAGIFEM<sup>®</sup>**

10. On information and belief, Teva admits that approved New Drug Application (“NDA”) No. 20908 is for estradiol vaginal tablets, in a 10 mcg dosage strength, which are sold in the United States under the trade name Vagifem<sup>®</sup>. Teva is without information sufficient to admit or deny the remaining allegations in paragraph 10 of the Complaint and therefore denies the same.

11. To the extent that paragraph 11 of the Complaint states conclusions of law, no

response is required from Teva. Teva admits that the '992 and '946 patents are listed in the Orange Book in connection with Vagifem<sup>®</sup>. Teva denies the remaining allegations in paragraph 11 of the Complaint.

**TEVA'S ANDA**

12. To the extent that paragraph 12 of the Complaint states conclusions of law, no response is required from Teva. Teva otherwise admits the allegations of paragraph 12 of the Complaint to which a response is required.

13. Teva admits that ANDA No. 206388 describes a generic equivalent of the estradiol vaginal tablets described in NDA No. 20908 and contains any required bioequivalence data. Teva denies the remaining allegations of paragraph 13 of the Complaint.

14. Teva admits the allegations of paragraph 14 of the Complaint, with the caveat that Teva's May 21, 2014 letter was sent to NNI, NNFCAG, and Novo Nordisk A/S, not just NNI and NNFCAG.

**COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,018,992**

15. Teva incorporates each of the preceding paragraphs as if fully set forth herein.

16. Teva admits that the filing of ANDA No. 206388 with a Paragraph IV Certification under the provisions of 21 U.S.C. §355(j) constitutes an act of "artificial infringement" of the '992 patent. Teva denies the remaining allegations of paragraph 16 of the Complaint.

17. Teva denies the allegations of paragraph 17 of the Complaint.

18. Teva denies the allegations of paragraph 18 of the Complaint.

19. Teva denies the allegations of paragraph 19 of the Complaint.

20. Teva denies the allegations of paragraph 20 of the Complaint.

**COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 5,860,946**

21. Teva incorporates each of the preceding paragraphs as if fully set forth herein.

22. Teva admits that the filing of ANDA No. 206388 with a Paragraph IV Certification under the provisions of 21 U.S.C. §355(j) constitutes an act of “artificial infringement” of the ‘946 patent. Teva denies the remaining allegations of paragraph 22 of the Complaint.

23. Teva denies the allegations of paragraph 23 of the Complaint.

24. Teva denies the allegations of paragraph 24 of the Complaint.

25. Teva denies the allegations of paragraph 25 of the Complaint.

26. Teva denies the allegations of paragraph 26 of the Complaint.

27. Teva denies each and every allegation contained in the Complaint not expressly admitted above. Teva denies that Plaintiffs are entitled to the judgment and relief prayed for in paragraphs A.-I. of the Complaint.

**AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

28. Teva has not infringed, does not infringe, and will not infringe (either directly or indirectly) any valid and enforceable claim of the ‘992 patent or the ‘946 patent.

**SECOND AFFIRMATIVE DEFENSE**

29. Each of the claims of the ‘992 patent and the ‘946 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or obviousness type double patenting.

**THIRD AFFIRMATIVE DEFENSE**

30. NNI should be dismissed from this action for lack of standing because Plaintiffs

have not averred in their Complaint that NNI has any right or interest in or to the '992 patent or '946 patent.

31. Teva specifically reserves the right to assert each and every other defense that may become evident during the course of discovery, including, but not limited to, inequitable conduct.

## **COUNTERCLAIMS FOR DECLARATORY JUDGMENT**

### **NATURE OF THE ACTION**

1. Teva incorporates by reference paragraphs 1 through 31 set forth above.
2. This is an action for a judgment declaring that the claims of U.S. Patent Nos. 7,018,992 ("the '992 patent") and 5,860,946 ("the '946 patent") are invalid, and that Teva has not infringed and will not infringe any asserted claim of the '992 patent or the '946 patent, either directly or indirectly, by engaging in the commercial manufacture, use, sale and/or importation of Teva's ANDA Product.

### **PARTIES**

3. Counterclaim-Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.
4. Counterclaim-Defendant Novo Nordisk Inc. ("NNI") has averred that it is a corporation organized and existing under the laws of Delaware, and maintains its principal place of business at 800 Scudders Mills Road, Plainsboro, New Jersey, 08536.
5. Counterclaim-Defendant Novo Nordisk FemCare AG ("NNFCAG") has averred that it is an entity organized and existing under the laws of Switzerland, having a place of business at Thurgauerstrasse 36-38, Zurich, Switzerland.

### **JURISDICTION AND VENUE**

6. This is an action for a declaration that the claims of the ‘992 and ‘946 patents are invalid and/or not infringed pursuant to the Patent Laws of the United States, 35 U.S.C. § 101 *et seq.* Accordingly, subject matter jurisdiction of this Court exists under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 28 U.S.C. §§ 1331 and 1338(a).

7. NNI and NNFCAG (collectively, “Counterclaim-Defendants”) have subjected themselves to the Court’s personal jurisdiction by filing the Complaint in the above action in this Court.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

### **FIRST COUNTERCLAIM**

#### **(Declaratory Judgment of Non-Infringement)**

9. Teva incorporates by reference paragraphs 1 through 8 as if fully set forth herein.

10. Counterclaim-Defendants allege that the ‘992 and ‘946 patents were assigned to Novo Nordisk A/S at the time of issuance, that Counterclaim-Defendant NNFCAG is currently the owner of all right, title, and interest in the ‘992 and ‘946 patents, that Counterclaim-Defendants are indirect, wholly owned subsidiaries of Novo Nordisk A/S, and that Teva infringes or will infringe the ‘992 and ‘946 patents.

11. As a consequence of the allegations of patent infringement made by Counterclaim-Defendants against Teva in their Complaint, there is an actual controversy between Counterclaim-Defendants and Teva, redressable by judgment of this Court, as to the alleged infringement of the ‘992 and ‘946 patents.

12. Teva is entitled to a judgment declaring that Teva has not infringed, contributed to the infringement of, or induced the infringement of any asserted claim of the ‘992 patent or ‘946

patent, and that the commercial manufacture, use, sale, offer for sale and/or importation of Teva's ANDA Product by Teva after obtaining approval from the FDA for those products, would not directly infringe, contribute to the infringement of, or induce the infringement of any claim of the '992 patent or the '946 patent.

13. Teva is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim-Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

### **SECOND COUNTERCLAIM**

#### **(Declaratory Judgment of Invalidity)**

14. Teva incorporates by reference paragraphs 1 through 13 as if fully set forth herein.

15. Counterclaim-Defendants allege that the '992 and '946 patents were assigned to Novo Nordisk A/S at the time of issuance, that Counterclaim-Defendant NNFCAG is currently the owner of all right, title, and interest in the '992 and '946 patents, that Counterclaim-Defendants are indirect, wholly owned subsidiaries of Novo Nordisk A/S, and that Teva infringes or will infringe the '992 and '946 patents.

16. As a consequence of the allegations of patent infringement made by Counterclaim-Defendants against Teva in their Complaint, there is an actual controversy between Counterclaim-Defendants and Teva, redressable by judgment of this Court, as to the validity of the '992 and '946 patents.

17. Teva is entitled to a judgment declaring that each of the claims of the '992 patent and the '946 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112 or 116, and the rules, regulations, and laws pertaining thereto, and/or

obviousness type double patenting.

18. Teva is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim-Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

**PRAYER FOR RELIEF**

WHEREFORE, Teva respectfully requests that this Court grant the following relief against Plaintiffs:

A. A judgment that Teva has not infringed, contributed to the infringement of, or induced the infringement of any asserted claim of the '992 patent or '946 patent, and that the commercial manufacture, use, sale, offer for sale and/or importation of Teva's ANDA Product by Teva after obtaining approval from the FDA for those products, would not directly infringe, contribute to the infringement of, or induce the infringement of any claim of the '992 patent or the '946 patent.

B. A judgment that each and every asserted claim of the '992 patent and the '946 patent is invalid;

C. A determination that this is an exceptional case and award Teva reasonable attorney fees and costs pursuant to 35 U.S.C. § 285;

D. Award Teva its costs and expenses in this action; and

E. Such other and further relief as this Court may deem just.

Dated: July 23, 2014

**LITE DEPALMA GREENBERG, LLC**

*Attorneys for Defendant  
Teva Pharmaceuticals USA, Inc.*

By: s/ Mayra V. Tarantino

Michael E. Patunas  
(mpatunas@litedepalma.com)  
Mayra V. Tarantino  
(mtarantino@litedepalma.com)  
Two Gateway Center, Suite 1201  
Newark, New Jersey 07102-5003  
(973) 623-3000 (telephone)  
(973) 623-0858 (facsimile)

Of Counsel  
**GOODWIN PROCTER LLP**  
Elaine H. Blais  
(eblais@goodwinprocter.com)  
John T. Bennett  
(jbennett@goodwinprocter.com)  
Srikanth K. Reddy  
(sreddy@goodwinprocter.com)  
Exchange Place  
53 State Street  
Boston, Massachusetts 02109  
(617) 570-1000 (telephone)  
(617) 523-1231 (facsimile)

**GOODWIN PROCTER LLP**  
David M. Hashmall  
(dhashmall@goodwinprocter.com)  
Joshua A. Whitehill  
(jwhitehill@goodwinprocter.com)  
The New York Times Building  
620 Eighth Avenue  
New York, NY 10018  
(212) 813-8800 (telephone)  
(212) 355-3333 (fax)

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

I hereby certify that the matter in controversy is related in part to another civil action pending in this Court. Plaintiffs are parties to the patent infringement suit captioned *Novo Nordisk Inc. et al. v. Amneal Pharmaceuticals, LLC et al.*, C.A. No. 3:13-cv-04915-MAS-DEA (D.N.J.), which concerns Amneal's ANDA for a generic version of VAGIFEM<sup>®</sup>. In that suit, Plaintiffs allege infringement by Amneal of the '992 patent, but, unlike in this case against Teva, Plaintiffs are not asserting the '946 patent against Amneal. In addition, a reissue application for the '992 patent is currently pending as United States Application No. 13/659,605 before the United States Patent and Trademark Office.

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other actions pending in any court, or of any other pending arbitrations or administrative proceedings.

Dated: July 23, 2014

**LITE DEPALMA GREENBERG, LLC**

*Attorneys for Defendant  
Teva Pharmaceuticals USA, Inc.*

By: s/ Mayra V. Tarantino  
Michael E. Patunas  
(mpatunas@litedepalma.com)  
Mayra V. Tarantino  
(mtarantino@litedepalma.com)  
Two Gateway Center, Suite 1201  
Newark, New Jersey 07102-5003  
(973) 623-3000 (telephone)  
(973) 623-0858 (facsimile)

*Of Counsel*

**GOODWIN PROCTER LLP**

Elaine H. Blais

(eblais@goodwinprocter.com)

John T. Bennett

(jbennett@goodwinprocter.com)

Srikanth K. Reddy

(sreddy@goodwinprocter.com)

Exchange Place

53 State Street

Boston, Massachusetts 02109

(617) 570-1000 (telephone)

(617) 523-1231 (facsimile)

**GOODWIN PROCTER LLP**

David M. Hashmall

(dhashmall@goodwinprocter.com)

Joshua A. Whitehill

(jwhitehill@goodwinprocter.com)

The New York Times Building

620 Eighth Avenue

New York, NY 10018

(212) 813-8800 (telephone)

(212) 355-3333 (fax)

**CERTIFICATE OF SERVICE**

I hereby certify that on July 23, 2014, I caused TEVA PHARMACEUTICALS USA, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS to be filed with the Clerk of the United States District Court for the District of New Jersey via CM/ECF.

Copies of the foregoing were caused to be served on July 23, 2014 upon the following attorneys:

**VIA ECF AND EMAIL**

**GIBBONS, PC**

David E. Delorenzi (ddelorenzi@gibbonslaw.com)  
One Gateway Center  
Newark, NJ 07102-5310  
Tel: (973) 596-4500

**VIA EMAIL**

**WHITE & CASE LLP**

Jeffrey J. Oelke (joelke@whitecase.com)  
Alison Hanstead (ahanstead@whitecase.com)  
Laura T. Moran (lmoran@whitecase.com)  
1155 Avenue of the Americas  
New York, NY 10036  
Tel: (212) 819-8200

*Attorneys for Plaintiffs*

s/ Mayra V. Tarantino

Mayra V. Tarantino